



4164-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-1025]

Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry and other stakeholders entitled "Emergency Use Authorization of Medical Products and Related Authorities." The purpose of this guidance is to explain FDA's current thinking on the authorization of the emergency use of certain medical products under certain sections of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) as amended or added by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA). The provisions in PAHPRA include key legal authorities to sustain and strengthen national preparedness for public health, military, and domestic emergencies involving chemical, biological, radiological, and nuclear (CBRN) agents, including emerging infectious disease threats.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

### Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-D-1025 for "Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders; Availability." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to Office of Counterterrorism and Emerging Threats, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, rm. 4343, Silver Spring, MD 20993-0002, 301-796-8510. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document. FOR FURTHER INFORMATION CONTACT: Carol Drew, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, rm. 4320, Silver Spring, MD 20993-0002, 301-796-8510 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

## I. Background

FDA is announcing the availability of a guidance for industry and other stakeholders entitled "Emergency Use Authorization of Medical Products and Related Authorities." This guidance explains FDA's general recommendations and procedures applicable to the authorization of the emergency use of certain medical products under sections 564, 564A, and 564B of the FD&C Act<sup>1</sup> (21 U.S.C. 360bbb-3, 360bbb-3a, and 360bbb-3b) as amended or added by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA)<sup>2</sup> (Pub.

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<sup>1</sup> Section 564 was first added to the FD&C Act by the Project BioShield Act of 2004 (Pub. L. 108-276).

<sup>2</sup> Section 3088 of the 21st Century Cures Act, signed into law by the President on December 13, 2016, (P.L. 114-255) amends sections 564, 564A, and 564B of the FD&C Act to add new authorities to: (1) Authorize emergency use of unapproved animal drugs; (2) make applicable other emergency use authorities (e.g., to issue emergency

L. 113-5). The provisions in PAHPRA include key legal authorities to sustain and strengthen national preparedness for public health, military, and domestic emergencies involving CBRN agents, including emerging infectious disease threats such as pandemic influenza. PAHPRA clarifies and enhances FDA's authority to support emergency preparedness and response and foster the development and availability of medical products for use in these emergencies. These medical products, also referred to as "medical countermeasures" (MCMs) include drugs (e.g., antivirals and antidotes), biological products (e.g., vaccines, blood products, and biological therapeutics), and devices (e.g., in vitro diagnostics and personal protective equipment).

This guidance finalizes the draft guidance "Emergency Use Authorization of Medical Products and Related Authorities" (April 2016) and replaces the following two guidance documents, "Emergency Use Authorization of Medical Products" (July 2007) and "Emergency Use Authorization Questions and Answers" (April 2009). The public comments received on the draft guidance have been considered and the guidance has been revised to clarify issues raised as appropriate. This guidance is intended to inform industry and government sponsors and other stakeholders involved in emergency response activities, including government agencies and public health and emergency response stakeholders, and FDA staff of FDA's general recommendations and procedures for:

- Issuance of Emergency Use Authorizations (EUAs) under section 564 of the FD&C Act;

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dispensing orders, waive compliance with current good manufacturing practices), make available Centers for Disease Control and Prevention emergency use instructions, and extend expiration dates to approved animal drugs; and (3) allow unapproved animal drugs to be held for emergency use. While much of what is described in this guidance will apply to these new authorities, this guidance does not by its terms reference them; FDA asks anyone interested in utilizing these authorities to contact FDA directly to discuss how to proceed. FDA plans to review these new authorities and address any new procedural issues raised as we develop more experience with these new authorities.

- Implementation of the emergency use authorities set forth in section 564A of the FD&C Act; and
- Reliance on the governmental pre-positioning authority set forth in section 564B of the FD&C Act.

Section 564 of the FD&C Act, as amended by PAHPRA, permits the Commissioner to authorize the emergency use of an unapproved medical product or an unapproved use of an approved medical product for certain emergency circumstances after the Department of Health and Human Services (HHS) Secretary has made a declaration of an emergency or threat justifying emergency use. That declaration by the HHS Secretary must in turn be based on a determination of an emergency or potential emergency or material threat associated with the CBRN agent by, respectively, the Secretary of Homeland Security, the Secretary of Defense, or the HHS Secretary. The Commissioner may issue an EUA to allow an MCM to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by a CBRN agent, or by a product used to diagnose, treat, or prevent such diseases or conditions, when available data meet specified criteria to support such uses and there are no adequate, approved, and available alternatives.

Section 564A, as added by PAHPRA, establishes streamlined mechanisms to facilitate preparedness and response activities involving certain FDA-approved MCMs without FDA issuing EUAs, which can be a resource-intensive process. These authorities, which apply only to eligible FDA-approved medical products intended for use during a CBRN emergency, include provisions that:

- Empower FDA to extend the expiration date of an eligible FDA-approved MCM stockpiled for use in a CBRN emergency, and establish appropriate conditions relating to such extensions, such as appropriate storage, sampling, and labeling;
- Permit FDA to waive otherwise applicable current good manufacturing practice requirements (e.g., storage or handling) to accommodate emergency response needs;
- Allow emergency dispensing of MCMs during an actual CBRN emergency event without requiring an individual prescription, or all of the information otherwise required, for each recipient of the MCM; and
- Permit the Centers for Disease Control and Prevention to create and issue "emergency use instructions" concerning the FDA-approved conditions of use for eligible products.

These authorities, and the definition of eligible products to which they apply, are discussed in this guidance.

To enable stakeholders to prepare for potential rapid deployment of MCMs during an actual CBRN emergency, section 564B (also added by PAHPRA) permits Federal, State, and local governments to pre-position (e.g., stockpile, forward-deploy) MCMs in anticipation of FDA approval or clearance, authorization of an investigational use, or the issuance of an EUA. This authority is also discussed in this document.

## II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on emergency use authorization of medical products and related authorities. It does not establish any rights for any

person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

### III. Electronic Access

Persons with access to the Internet may obtain the guidance at <http://www.fda.gov/RegulatoryInformation/Guidances/default.htm>, <http://www.regulations.gov>, or <http://www.fda.gov/medicalcountermeasures>

### IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). This guidance refers to previously approved collections of information. These collections of information have been approved under OMB control numbers 0910-0308, 0910-0230, 0910-0471, 0910-0014, 0910-0078 and 0910-0595. The collection of information in this guidance was approved under OMB control number 0910-0595.

Dated: January 10, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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